The committee will discuss biologics license application (BLA) 761042, for GP2015, a proposed biosimilar to Amgen Inc’s Enbrel (etanercept) submitted by Sandoz, Inc. The proposed indications (uses) for this product are (1) Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA)((in combination with methotrexate (MTX) or used alone); (2) reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older; (3) reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (in combination with MTX in patients who do not respond adequately to MTX alone); (4) reducing signs and symptoms in patients with active ankylosing spondylitis; (5) treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
APPLICANT PRESENTATIONS (cont.)

Clinical Confirmation of GP2015 Equivalence to Enbrel®  
Malte Peters, MD  
Global Head of Clinical Development  
Sandoz Biopharmaceuticals  

Use in Clinical Practice  
Jonathan Kay, MD  
Timothy S. and Elaine L. Peterson Chair in Rheumatology  
Professor of Medicine  
Director of Clinical Research, Rheumatology  
University of Massachusetts Medical School  

Conclusions  
Mark McCamish, MD, PhD  

10:00 a.m.  Clarifying Questions to Applicant  

10:15 a.m.  BREAK  

10:30 a.m.  FDA PRESENTATIONS  

GP2015 Product Quality Review  
Peter L. Adams, PhD  
CMC Product Quality Reviewer  
Division of Biotechnology Review and Research 1  
Office of Biotechnology Products  
Office of Pharmaceutical Quality, CDER, FDA  

GP2015 Statistical Equivalence Testing for Bioactivity  
Meiyu Shen, PhD  
CMC Statistical Reviewer  
Division of Biometrics VI  
Office of Biostatistics (OB)  
Office of Translational Sciences (OTS), CDER, FDA  

GP2015 Product Quality Review (cont.)  
Peter L. Adams, PhD  

Clinical Pharmacology Review  
Yunzhao Ren, MD, PhD  
Clinical Pharmacology Reviewer  
Division of Clinical Pharmacology II  
Office of Clinical Pharmacology, OTS, CDER, FDA  

Clinical Efficacy Review  
Kathleen Fritsch, PhD  
Mathematical Statistician  
Division of Biometrics III, OB, OTS, CDER, FDA
AGENDA (cont.)

FDA PRESENTATIONS (cont.)

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<td>12:00 p.m.</td>
<td>Clarifying Questions to FDA</td>
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<td>2:45 p.m.</td>
<td>Charge to the Committee</td>
<td>Nikolay P. Nikolov, MD</td>
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<td>BREAK</td>
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